

O. Haynes
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7.18.03

Serial No. 09/809,428

Docket No.: 1268-121

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Baruch GLATTSTEIN

Serial No. 09/809,428

Filed: March 16, 2001

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: Group Art Unit: 1743

: Examiner: S. P. Siefke
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For: MOLDED CASING FOR A TEST KIT

SUBMISSION AND RESPONSE

ASSISTANT COMMISSIONER FOR PATENTS
Washington, D. C. 20231

Sir:

The following is a response to the Official Action dated January 7, 2003. The response date has been extended for three (3) months until July 7, 2003 by reason of a petition and a fee therefore filed herewith. There is being filed herewith a Request for Continuing Prosecution. This document will serve as the submission required to be filed with an RCE. It is believed that the extension of response period petitioned for in an accompanying paper is sufficient to maintain the pendency of this application. It is believed that the fee being paid herewith is correct and sufficient. If it is incorrect and/or insufficient, kindly charge the amount needed to make it correct and sufficient to the undersigned attorneys' deposit account 07-1337.

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Reconsideration of the patentability of the claims of the above referenced application is solicited in view of the following comments.

The Examiner's indication of allowable subject matter of claims 16 and 22 is noted with appreciation.

Claims 1-22 are pending in the application.

The patentability of all of the claims of this application, save allowable claims 16 and 22, has been rejected as either anticipated by the disclosure of the cited '097 patent or as obvious in view of the disclosure of this reference alone or in combination with other reference(s). These rejections are respectfully traversed because they are based on attributions to the disclosure of the '097 patent that are not there.

Some { The present invention relates to a disposable test kit for use in the field where skilled personnel may not be always available. Therefore, an objective of the present invention is to allow even **unskilled** people to perform the tests. Another objective of the present invention is to allow the test results to be evaluated, in the field, by a person not necessarily skilled in chemical testing procedures. These objectives are achieved by a unique feature the present invention, i.e., the claimed **distinct** reaction chamber. See independent claims 1, 9, 11. The '097 reference clearly fails to disclose, teach or suggest a structure that is suited to this use.

The '097 patent is directed to a housing for one or more reagents. The reagents housed in the disclosed structure are intended to be removed from the structure and used in some other apparatus (see columns 9, 10 and 11). More importantly, the instant claimed structure does not find correspondence in the disclosure of the principal reference. The instant claims call for a distinct

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reaction chamber, identified by the reference numeral 3 in the drawing of this application. Note that the reaction chamber 3 is empty of material until an ampoule, that is contained in a distinct cell 4, 5 and/or 6, is broken and its contents allowed to proceed through a respective passageway, 4a, 5a and/or 6a, from the respective cell(s) 4, 5 and/or 6 to the reaction chamber 3. The passageway(s) are designed to exclude the broken glass of the fractures ampoule, either because of the small size of the passageway or because a filter medium is interposed between the cells and the reaction chamber.

By way of contrast and differentiation, Figs. 2 and 16 of the '097 reference disclose a single chamber 32 or 34 that houses a reconstituting liquid as well as an ampoule that preferably contains a powder. For ease of reference, only the chamber 32 will be addressed in the following analysis. It is understood that the other chamber 34 and its associated elements behaves in exactly the same manner. Once the chamber 32 is closed, there is no access to or from the chamber 32 except through the rocker valve 20. The chamber 32 is filled with a reconstituting fluid and also contains a frangible ampoule 14. The reference discloses only this single chamber housing both the reconstituting fluid and the frangible ampoule. Therefore applicants' claims, that require two distinct volumes, that is a separate cell (one chamber housing a frangible ampoule) and a separate reaction chamber operatively coupled by an opening (a narrow passageway) joining them, are not anticipated by the disclosure of the '097 reference. The remaining figures of this reference are not pertinent to the patentability of the instant claimed invention.

It is interesting to note that in the instant claims, the opening, or narrow passageway, between the reaction chamber and the ampoule containing cells is intended (and recited) to prevent the pieces of glass from the fractured ampoule from getting from the cells into the reaction

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chamber. However, the screen or filter of the reference does not prevent the broken glass pieces of ampoule from intermixing with the rest of the composition in the chamber 32. The screen or filter 16 prevents the glass shards from being extracted from the chamber by the aspiration probe, but does not prevent them from being in the reaction chamber.

The reference does not disclose any passageway between cell(s) containing an ampoule and a separate reaction chamber. The claims require an "opening" between the cells and the reaction chamber. The reference discloses no such opening. The ampoule is located in the chamber that houses the reconstituting fluid. If one wished to analogize, the chamber 32 of the reference could be considered to be comparable to the reaction chamber 3 of the instant claims. There is no disclosure in the reference of a separate chamber housing the ampoule as is required in the instant claimed invention.

The examiner has asserted that the '097 reference discloses an inlet leading from the outside to the inner space of the reaction chamber 32 **for inserting a sample of a tested material**. Although the reference's specification and claims have been carefully reviewed, no allegation of any such use has been found. There is provision in the reference for aspirating the contents of the chamber 32 after the ampoule has been broken and the reconstituting liquid and the contents of the fractured ampoule have been thoroughly mixed. The reference, however, takes this aspirated composition and suggests its use elsewhere. There is simply no disclosure of inserting a "tested sample" into the chamber 32 either before or after the ampoule has been broken.

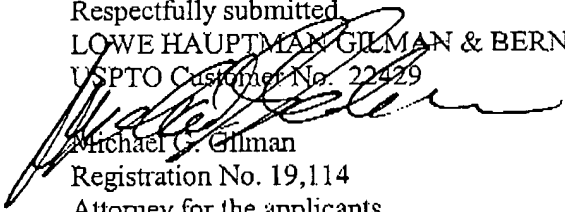
In claim 11, there is specified an inlet leading from the outside into the reaction chamber. This inlet is intended to permit the introduction of samples to be tested directly into the reaction

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chamber. It is clear that the valving means 21 of the reference is not the same as or comparable to the inlet means 7 claimed in the instant application (claim 11). In the instant invention, the claimed device is intended for use in the field, often by poorly trained personnel. The use of the instant device is to ascertain the biological or chemical nature of some sample found in the field. To do so, the sample being tested is introduced into the reaction chamber, and the ampoule of reagent is broken so that its contents flow from its housing (cell) through a restrictive opening into effectively contact with the sample being tested. In the reference, no sample is being tested in the disclosed device. The ampoule is housed in the reaction chamber along with a reconstituting fluid. The ampoule is broken and its contents are mixed with the reconstituting fluid. This mixture is then withdrawn from the device and used elsewhere for whatever purpose is intended. Clearly, the reference device and the instant device are structurally different and operate in a completely different manner.

The secondary references clearly do not make up for the deficiencies in the disclosure of the '097 patent. It is therefore urged that the examiner reconsider her position and withdraw all of the rejections.

Respectfully submitted,
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